5.5 and not more than 8.0. It passes the identity test. The ceftizoxime sodium used conforms to the standards prescribed by § 442.17(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ceftizoxime sodium used in making the batch for ceftizoxime content, moisture, pH, identity, and crystallinity.

(*b*) The batch for ceftizoxime content, sterility, pyrogens, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research, of:

(*a*) The ceftizoxime sodium used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assays.* Thaw the sample as directed in the labeling. The sample solution used for testing must be at room temperature.

(1) *Ceftizoxime content.* Proceed as directed in § 436.345 of this chapter, except prepare the sample solution and calculate the ceftizoxime content as follows:

(i) *Sample solution.* Using a suitable hypodermic needle and syringe, transfer an accurately measured representative portion from each container, equivalent to 40 milligrams of ceftizoxime, to a 100-milliliter volumetric flask. Dilute to volume with pH 7.0 buffer solution and mix. Transfer 10.0 milliliters of this solution to a 200-milliliter volumetric flask, add 5.0 milliliters of internal standard solution, dilute to volume with pH 7.0 buffer solution, and mix.

(ii) *Calculations.* Calculate the milligrams of ceftizoxime per milliliter of sample as follows:

$$\text{Milligrams of ceftizoxime per milliliter} = \frac{R_u \times P_s \times d}{R_s \times 1{,}000}$$

where:

R_u=Area of the ceftizoxime peak in the chromatogram of the sample (at a retention time equal to that observed for the standard)/Area of the internal standard peak;

R_s=Area of the ceftizoxime peak in the chromatogram of the ceftizoxime working standard/Area of the internal standard peak;

P_s=Ceftizoxime activity in the ceftizoxime working standard solution in micrograms per milliliter; and

d=Dilution factor of the sample.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, except inject a sufficient volume of the undiluted solution to deliver 50 milligrams of ceftizoxime per kilogram.

(4) *pH.* Proceed as directed in §436.202 of this chapter, using the undiluted solution.

(5) *Identity.* The high-pressure liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the ceftizoxime working standard.

[49 FR 49286, Dec. 19, 1984; 50 FR 253, Jan. 3, 1985, as amended at 55 FR 11583, Mar. 29, 1990]

§ 442.218 Cefuroxime injectable dosage forms.

§ 442.218a Sterile cefuroxime sodium.

The requirements for certification and the tests and methods of assay for sterile cefuroxime sodium packaged for dispensing are described in § 442.18a.

[48 FR 38461, Aug. 24, 1983. Redesignated at 54 FR 40654, Oct. 3, 1989]

§ 442.218b Cefuroxime sodium injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefuroxime sodium injection is a frozen, aqueous, iso-osmotic solution of cefuroxime sodium which may contain one or more suitable and harmless buffer substances and a tonicity adjusting agent. Each milliliter